Approved for use through 10/31/2002, 0M8 095
Patent and Trademark Office; U.S. DEPARTMENT OF COMM
collection of information unless it displays a valid 0M8 control number

UTILITY
PATENT APPLICATION
TRANSMITTAL

Please type a plus sign (+) inside this box +

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a coll 661005.90268 Attorney Docket First Inventor Michael C. Barney

	TRANSMITTAL	ANTIMICROBIAL DIAPERS AND WET WIPES							
(Only for new r	nonprovisional applications under 37 CFR 1 53(b))	ess Mail EJ636885455US							
	APPLICATION ELEMENTS appter 600 concerning utility patent application cont	ADDRESS TO: Commissioner for Patents Box Patent Application Washington, D.C. 20231							
2. Ap Se 3. X Sp - C - S - F - E	e transmittal Form born a rogal and a duplicate for fee processing) plicant claims small entity status e 37 CFR 1.27. Editional form of the status of the small entity status e 37 CFR 1.27. Editional form of the small entity status or expected arrangement set forth below! In the status of the small entity of the small entit	7. CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix) 8. Nucleotide and/or Amno Acid Sequence Submission (Irapplicable, ell necessary) a. Computer Readable Form (CRF) b. Specification Sequence Listing on CD-R (2 Copies); or paper c. Statements verifying identity of above copies							
- E	Brief Description of the Drawings (if filed	,	ACCOMPANYING APPLICATION PARTS						
4.	Detailed Description Claim(s) Abstract of the Disclosure awing(s) (35 USC 113) [Total Sheets Declaration [Total Pages [Newly executed (original or copy) Copy from prior Application (37 CFR 1, 67 DELETION OF INVENTORIS) DELETION OF INVENTORIS) and 1,33(b). Bickind Data Sheet. Se 37 CFR 1,78	(d)(2)	9. X Assignment Papers (cover sheet & documents) 10. 37.CFR 3.738b Statement 11. 27.CFR 3.738b Statement 12. 38. 38. 38. 38. 38. 38. 38. 38. 38. 38						
Application Con Prior ap	in Data Sheet under 37 CFR 1.76 tinuation Divisional Continu pplication information: Examiner:	ation-ın-g	Group/Art Unit:						
under Box 5b, i	s considered a part of the disclosure of the ac	company	of the prior application, from which an oath or declaration is supplied ring continuation or divisional application and is hereby incorporated by as been inadvertently omitted from the submitted application parts.						
			NDENCE ADDRESS						
Customer I	Number or Bar Code Label {Insert Customer	No. or A	ttach bar code label here) Or 🛣 Correspondence address below						
NAME	David G. Ryser								
ADDRESS	Quarles and Brady LLP 411 East Wisconsin Avenue								
CITY	Milwaukee	STAT	111000 1011 1 1 00202 7730						
COUNTRY	USA TEL	EPHON	E (414) 277-5717 FAX (414) 277-3552						

Name David G. Ryser Registration No. (attorney/Agent) 36,407 Signature Date: October 20, 2000 Burden Hour Statement: This form is estimated to take 0.2 plught to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete the form equiple to the form of the complete to the complete to the form of the complete to the comp

QBMKE\4622545.2

Signature

FEE TRANSMITTAL for FY 2001

Patent fees are subject to annual revision. Small Entity payments must be supported by a small entity statement

otherwise large entity fees must be paid, See Forms PTO/SB/09-12
See 37 C.F.R. §§1.27 and 1.28 TOTAL AMOUNT OF PAYMENT \$710.00

Patent and Tradema	IK UTICE: U.S. DEPARTIVIENT OF	GOIMIN	Н
Con	nplete if Known	33,	
Application Number		3. 11.	
Filing Date	October 20, 2000	3 (
First Named Inventor	Michael C. Barney	900	
Group Art Unit		-	
Examiner Name			
Attorney Docket Number	661005.90268		

\$1,10,00		
METHOD OF PAYMENT (check one)	FEE CALCULATION (continued)	
The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:	3. ADDITIONAL FEES	
Deposit Namber 17-0055	.arge Entity Small Entity Fee Fee Fee Fee Code (\$) Code (\$) Fee Description	Fee Paid
Deposit Account Name Quarles & Brady LLP	105 130 205 65 Surcharge - late filing fee or oath	
	127 50 227 25 Surcharge - late provisional filing fee or cover sheet	
X Charge Any Additional Fee Required Under 37 CFR 1 16 and 1 17	139 130 139 130 Non-English specification	
	147 2,520 147 2,520 For filing a request for reexamination	
2. Payment Enclosed:	112 920 112 920 Requesting publication of SIR prior to Examiner action	
Check Money Other	113 1,840 113 1,840 Requesting publication of SIR after Example action	iner
FEE CALCULATION	115 110 215 55 Extension for reply within first month	
1. BASIC FILING FEE	116 390 216 195 Extension for reply within second month	
Large Entity Small Entity	117 890 217 445 Extension for reply within third month	
Fee Fee Fee Fee Code (\$) Fee Description Fee Paid	118 1,390 218 695 Extension for reply within fourth month	
101 710 201 355 Utility filing fee \$710.00	128 1,890 228 945 Extension for reply within fifth month	
106 320 206 160 Design filing fee	119 310 219 155 Notice of Appeal	
107 490 207 245 Plant filing fee	120 310 220 155 Filing a brief in support of an appeal	
· · · · · · · · · · · · · · · · · · ·	121 270 221 135 Request for oral hearing	
	138 1,510 138 1,510 Petition to institute a public use proceeds	ng
114 150 214 75 Provisional filing fee	140 110 240 55 Petition to revive unavoidably abandoned application	
SUBTOTAL (1) (\$)710.00	141 1,240 241 620 Petition to revive unintentionally abandor application	red
2 CLAIMS Extra below Fee Paid	142 1,240 242 620 Utility issue fee (or ressue)	
	143 440 243 220 Design issue fee	
	144 600 244 300 Plant issue fee	
	122 130 122 130 Petitions to the Commissioner	
Multiple Dependent Claims 0 = 0	123 50 123 50 Petitions related to provisional application	ns
** or number previously paid, if greater, For reissues see below	126 240 126 240 Submission of Information Disclosure Str	nt
Large Entity Small Entity Fee Fée Fee Fee Code (\$) Code (\$) Fee Description	581 40 581 40 Recording each patent assignment per property (times number of properties)	
103 18 203 9 Claims in excess of 20	146 710 246 355 Filling a submission after final rejection (37 CFR 1.129(a))	
102 80 202 40 Independent claims in excess of 3	149 710 249 355 For each additional invention to be exami	ned
104 270 204 135 Multiple dependent claim	179 710 270 355 Request for Continued Examination (RCE	
109 80 209 40 Reissue independent claims over original patent	169 900 169 900 Request for expedited examination of a design application	
110 18 210 9 Reissue claims in excess of 20 and over original patent	Other fee (specify)	
SUBTOTAL (2) (\$) 0	Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$)	
SUBMITTED BY	Complete (if applicable)	
Typed or Printed Name David G. Ryser Registration (Attorney/Ag	on 36,407 Telephone 414-277-57	17

Date

October 20, 2000

10

15

20

30

ANTIMICROBIAL DIAPERS AND WET WIPES

CROSS REFERENCES TO RELATED APPLICATIONS

Not applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH Not applicable.

BACKGROUND OF THE INVENTION

This invention relates to the application of specific antimicrobial agents to diapers and wet wipes for the protection of infants from strains of the bacterium *Staphylococcus aureus*, which is known to be a causative agent of toxic shock syndrome (TSS). Toxic shock syndrome is a severe, toxin-induced disease caused by infection with toxic shock syndrome toxin-1 (TSST-1) (landolo, <u>Ann. Rev. of Micro.</u> 43:275-402, 1989) which is produced by *Staphylococcus aureus*, and is characterized by sudden onset of symptoms including high fever, chills, rash, vomiting and/or diarrhea, and a rapid drop in blood pressure, which often leads to shock. While most commonly seen in menstruating women, in whom the primary site of infection is vaginal, the syndrome has also been reported in infants, children, men, and nonmenstruating women at a lower frequency rate. In such cases, skin wounds or *Staphylococcus aureus* infection in other sites in the body are believed to be the cause of TSS. The rate of incidence of the syndrome in the United States is about two cases per 10,000 persons annually.

While the disease may be treated with antibiotics and by administration of intravenous fluids to maintain blood pressure, many persons suffering from toxic shock syndrome may not receive appropriate medical intervention before serious complications result, due to the sudden onset of the syndrome. This is particularly true in the case of infants and children. Typically, such

10

15

20

25

30

complications may include kidney failure, heart failure, liver failure, and profound shock.

Because TSS has such a rapid onset, and may be life-threatening, there is a very strong emphasis on disease prevention, with most of the concentration being upon menstruating women, who are at increased risk of developing TSS through the use of highly absorbent tampons or barrier contraceptives. Various approaches to preventing the development of toxic shock syndrome from tampon use have been advanced, including incorporating bactericidal or bacteriostatic agents such as antibiotics or phenol into tampons to inhibit grown of <code>Staphylococcus aureus</code>; incorporating agents which prevent the production of TSST-1, or inactivate TSST-1; and mechanical improvements to tampons which prevent harmful bacteria from being introduced into or colonizing within the vagina.

A number of U.S. Patents have issued relative to this matter, including U.S. 4,405,323, the content of which is incorporated herein by reference, as if fully set forth herein, which discloses a tampon having an antibacterial agent such as povione-iodine, mercury, zinc, penicillin, erythromycin, or nitrofurazone, incorporated therein. U.S. Patent 4,431,427, the content of which is incorporated herein by reference, as if fully set forth herein, discloses a tampon incorporating a water-soluble acid, such as citric, glycolic, malic, tartaric, or lactic acid, in an amount sufficient to maintain a pH of less than 4.5 in the fluids absorbed in a tampon, so as to inhibit growth of pathogenic bacteria.

It is also known that some hop acids produced in the brewing of beer can inhibit the growth of microorganisms. U.S. Patent 5,082,975, the content of which is incorporated herein by reference, as if fully set forth herein, discloses that the hop acid hexahydrolupulone can inhibit the growth of *Lactobacillus* without inhibiting yeast. Similarly, U.S. Patent 5,455,038, the content of which is incorporated herein by reference, as if fully set forth herein, teaches that Listeria in a medium or in food may be inhibited by contact with an effective amount of hexahydrocolupulone, tetrahydroiso-

10

15

20

25

30

acids are relatively inexpensive, making their use to inhibit growth of organisms attractive. Also, resistance of *Staphylococcus aureus* has not been described as has the resistance to various antibiotics. The term "tetrahydro-isohumulone" as used herein includes a mixture of tetrahydroisohumulone, tetrahydroisoadhumulone and tetrahydroisocohumulone. The mixture is commercially available, or can be prepared for example by use of the method of the Cowles *et al.* U.S. Patent 4,644,084, the content of which is incorporated herein by reference, as if fully set forth herein. The hexahydro-colupulone is a known compound which can be made by the chemical hydrogenation of colupulone with platinum (IV) oxide as the catalyst as described by W. Reidl, J. Nickl, *Ber*, 89 (1956) p. 1863, or J. F. Carson, J. Am. Chem. Soc., 73 (1951) p. 1850.

Further, Nutter *et al.* disclosed in U.S. Patent 5,827,895, the content

humulone, or a salt of hexahydrocolupulone or tetrahydroisohumulone. Hop

of which is incorporated herein by reference, as if fully set forth herein, that hexahydrolupulones and hexahydrocolupulones may be used to inhibit the growth of *Staphylococcus aureus*. Nutter *et al.* also reported that the antimicrobial activity of hexahydrolupulones is highly specific for gram positive bacteria, such as *Staphylococcus aureus*.

In addition, Todd et al, in U.S. Patent 5,166,449, the content of which is incorporated herein by reference, as if fully set forth herein, note the anti-bacterial activity of beta acids (lupulone), as a constituent of hops, and methods for their conversion to tetrahydroiso-alpha and hexahydro-beta acids. The patent also teaches the use of such compounds for inhibition of the bacterium Lactobacillus.

However, no methods have to date been found to effectively eliminate or inhibit growth of *Staphylococcus aureus*, or toxins produced thereby, in skin wounds or other sites of the body, particularly in infants. Since infants are sensitive to TSS, and infants of diaper wearing age particularly so, a means to prevent TSS associated with infection from skin contact has been sought.

10

15

20

25

30

BRIEF SUMMARY OF THE INVENTION

The present invention provides a means for prevention of TSS in infants of diaper wearing age, by provision of diapers and wet wipes for use in cleansing of infants, wherein said diapers and wet wipes contain an antimicrobial compound effective against TSST-1, and thus against TSS. It has now been discovered that certain hop acid derivatives are highly bactericidal to gram positive bacteria, and are particularly effective at killing *Staphylococcus aureus*, the causative agent of toxic shock syndrome, at extremely low concentrations. These derivatives are tetrahydroiso-alpha acids, and/or hexahydro-beta acids, and mixtures thereof. Both of these derivatives have now been found to have greatly enhanced antimicrobial properties compared to the hop acids, humulone and lupulone. The two derivatives may be used independently, or together, with positive effect.

When applied to diapers, particularly disposable diapers, these derivatives essentially eliminate the growth of *Staphylococcus aureus* and toxins associated therewith, including toxic shock syndrome toxin-1,in diapers in contact with the skin. These compositions may also be applied to wet wipes used to clean the infant when changing diapers, and will inhibit *Staphylococcus aureus* on skin surfaces, thus reducing the risk of toxic shock syndrome in infants of diaper wearing age.

It is thus an advantage of the present invention to provide an inexpensive method for inhibiting the occurrence of TSS in infants. It is a further advantage of the present invention to provide a wet wipe suitable for use not only on infants of diaper wearing age, but for use on any skin wound or area of possible infection, which is antimicrobial against Gram-positive bacteria, and particularly against Staphylococcus aureus. A still further advantage is that the effective medium is a naturally occurring derivative of a natural source, and is readily biodegradable as well as being safe for human consumption, in concentrations which will kill Staphylococcus aureus as well as other Gram-positive bacteria.

10

15

20

25

30

DETAILED DESCRIPTION OF THE INVENTION

Toxic shock syndrome is a serious, potentially fatal illness that occurs with sudden onset, and occurs primarily in menstruating women. However, toxic shock syndrome is also known to effect infants, children, men, and non-menstruating women, primarily from skin wounds or infection of other sites in the body by Staphylococcus aureus and the toxic shock syndrome toxin-1. It has now been found that certain specific hop-acid derivatives, specifically tetrahydroisoalpha acids and hexahydro-beta acids, will inhibit the growth of Staphylococcus aureus and other Gram-positive bacteria when applied topically to a skin wound, or when incorporated in a diaper or other dressing, such as a bandage, in contact with the skin.

Since toxic shock syndrome in infants has been attributed to the growth of Staphylococcus on baby diapers, the addition of anti-Staphylococcus compounds, specifically tetrahydroiso-alpha acids and hexahydro-beta acids, to materials used in disposable baby diapers as well as to wet wipes used to clean the baby during diaper changes would inhibit Staphylococcus aureus and reduce the risk of toxic shock syndrome. Tetrahydroiso-alpha acids and hexahydro-beta acids also inhibit all other Gram-positive bacteria tested, and to a lesser amount some Gram-negative bacteria, which may also colonize and grow in disposable baby diapers. Therefore, there would be an added benefit of helping to eliminate bacteria other than Staphylococcus that could cause potential infections.

The preferred embodiment of the present invention thus comprises incorporating a safe and effective concentration of tetrahydroiso-alpha acid, hexahydro-beta acid, or mixtures thereof, in the surface layer of a disposable diaper, or in the wetting solution of a wet wipe, to combat the growth of bacteria on infants. By the term "an effective amount of the compound" it is meant that sufficient of the compound is present to provide the desired antimicrobial effect, but not so much as to cause any undesirable result, or to be prohibitively expensive. By the term antimicrobial, it is meant that the compo-

10

15

20

25

sition, at a minimum, inhibits the growth of bacteria, and preferably, destroys such bacteria as are present.

It is known in the brewing industry that some hop acids can inhibit the growth of microorganisms that can cause spoilage in beer. Hop acids are relatively inexpensive, making their use in food products to inhibit growth of organisms attractive. From this recognition came the discovery that tetrahydroiso-alpha acids and hexahydro-beta acids have bactericidal or bacteriostatic activities against <code>Staphylococcus aureus</code>. This makes it possible to selectively inhibit <code>Staphylococcus aureus</code> in a culture by contacting the culture with a tetrahydroiso-alpha acid or hexahydro-beta acid in a concentration effective to inhibit <code>Staphylococcus aureus</code>.

To selectively inhibit Staphylococcus aureus in culture by contacting the culture with a tetrahydroiso-alpha acid or hexahydro-beta acid, the concentration of tetrahydroiso-alpha acid or hexahydro-beta acid is preferably is in the range of from about 0.1 ppm to about 100 ppm, based upon the total culture. More preferably, the concentration of tetrahydroiso-alpha acid or hexahydro-beta acid is about is in the range of from about 0.2 ppm to about 50 ppm of the total culture. Since the hop compounds utilized are relatively stable compounds, they may be used as a solution sprayed on the finished diapers, or applied as a liquid during manufacture of the diapers, and subsequently dried. Once the compounds are dried, with sufficient compound remaining in situ to provide an effective amount of the compound on the diaper in use, they are relatively stable.

The preferred mode of contacting the culture comprising Staphylococcus aureus with the hop acids is to place an absorbent material containing an effective amount of the hop acids in contact with or in proximity to the culture.

The following non-limiting examples are intended to be purely illustrative.

1.5

20

25

5

Examples

Minimal inhibitory concentration (MIC) assays of several hop compounds were conducted using a *Staphylococcus aureus* species as the test microorganism. The MCl assays for *Staphylococcus aureus* were conducted in Difco trypticase soy broth (TSB) tubes. A 0.1 ml aliquot of a 1% (w/w) solution of each hop acid in alcohol was added to a tube of sterile TSB broth to give a final concentration of 100 ppm of the hop. This solution was serially diluted in tubes with sterile broth using a two-fold dilution series. A second dilution series prepared as above, but using 0.1 ml alcohol without hop acid, was used as a positive control of bacterial growth. Each tube was inoculated with a fresh culture (10⁴ cells) of a *Staphylococcus aureus* species in TSB broth. The pH of the TSB was adjusted to pH 7.0, pH 6.0, or pH 5.0 using hydrochloric acid. The tubes were incubated aerobically at 37°C for three days and growth was evaluated by visually assessing and scoring the development of turbidity in the broth.

The results of MIC assay of tetrahydroiso-alpha acids and hexahydrobeta acids on *Staphylococcus aureus* and are shown in Table 1.

As can be seen from Table 1, Staphylococcus aureus is very sensitive to both tetrahydroiso-alpha acids and hexahydro-beta acids. Staphylococcus aureus showed no growth or possibly very weak growth at tetrahydroiso-alpha acid or hexahydro-beta acid concentrations as low as 1.56 ppm at a neutral pH. Sensitivity of Staphylococcus aureus appears to increase under acidic conditions, with the minimum inhibitory concentration decreasing to 0.78 ppm at pH 6.0 and to 0.2 ppm at pH 5.0.

10

15

20

Table 1

	MIC Assays of Tetrahydroiso-alpha Acids and												
	Hexahydro-beta Acids using Staphylococcus aureus												
	TSB at	pH 7.0	TSB at	pH 6.0	TSB at pH 5.0								
Concentra- tion (ppm)	Tetra	Hexa	Tetra	Hexa	Tetra	Hexa							
100	No growth	No growth	No growth	No growth	No growth	No growth							
50	No growth	No growth	No growth	No growth	No growth	No growth							
25	No growth	No growth	No growth	No growth	No growth	No growth							
12.5	No growth	No growth	No growth	No growth	No growth	No growth							
6.25	No growth	No growth	No growth	No growth	No growth	No growth							
3.125	No growth	No growth	No growth	No growth	No growth	No growth							
1.56	+/- Growth	+/- Growth	No growth	No growth	No growth	No growth							
0.78	+ Growth	+ Growth	No growth	No growth	No growth	No growth							
0.39	++ Growth	++ Growth	+/- Growth	No growth	No growth	No growth							
0.2	+++	+++	++ Growth	+ Growth	No growth	No growth							
	Growth	Growth											
0	+++	+++	+++	+++	+++	+++							
	Growth	Growth	Growth	Growth	Growth	Growth							

From this experimentation, it may be clearly seen that both tetrahydroiso-alpha acids and hexahydro-beta acids have strong antimicrobial or antibacterial properties, and are candidates for use in any application where they might be useful to combat Staphylococcus aureus, the primary causative agent in toxic shock syndrome.

For the purpose of applying these agents to combat toxic shock syndrome in infants, it was determined that directly incorporating them into the fabric of the diaper, or into the liquid present in a wet wipe to be used for cleansing of the infant, offered the greatest advantages. Various methods are known in the art for the application of liquid compositions to absorbent fabrics, and such methods are not considered as part of the present invention. Similarly, the addition of various components to the cleansing

25

30

5

agents used in wet wipes is well known in the art, and not considered part of the present invention. Rather, the present invention is related to the selection of the specific antimicrobial compositions used, i.e. the tetrahydroiso-alpha acids and hexahydro-beta acids, provided that sufficient of the composition is provided so as to be an effective antimicrobial composition when in contact with a site subject to microbial growth. The specified compositions are readily available as by-products of the brewing industry, at relatively low cost. Being products of naturally occurring compositions, these acids are biodegradable. and safe for human usage, particularly as envisioned.

For application to a disposable diaper, it is proposed that a suitable mixture incorporating an effective concentration of the tetrahydroiso-alpha acid, hexahydro-beta acid, or a mixture thereof, be applied to a woven or non-woven cellulose-containing substrate, such as a moisture absorbent fabric of the type commonly used for diapers. Such fabrics are well known in the art, and any suitable such material may be used, including those containing super absorbent materials. It is also possible, although less advantageous, to include the antimicrobial composition of the invention in conventional cotton or other fabric diapers suitable for washing and re-use, although the antimicrobial composition will be removed from the fabric during normal washing.

The tetrahydroiso-alpha and hexahydro-beta acids employed are known to be soluble in water. Alternatively, they are also soluble in such materials as ethanol (and other alcohols), propylene glycol, glycerine, and polyols, or mixtures thereof with or without water. Such materials are quite suitable for, and are frequently employed in, diapers and wet wipes. Since the compounds are poorly soluble in plain water, alcohols are frequently used to prepare a solution. When water is used, it may be adjusted to a mildly alkaline pH to increase the solubility of the compounds.

The hop acid antimicrobials may be incorporated into the absorbent fabric, such as a disposable diaper, in conventional fashion, such as by passage of the fabric from a supply roll, into a pad bath containing an

20

25

30

5

appropriate concentration of the antimicrobial in solution, through a nip roll to remove excess liquid, and into a dryer to dry the fabric to the touch, at temperatures adequate to remove excess water and other carriers without causing deterioration or conversion of the hop acid to an ineffectual form. To achieve a suitable disposable diaper in accordance with the invention, the diaper, after drying, and as packaged for consumer purchase, should have a sufficient amount of antimicrobial impregnated therein to be effective in combating Staphylococcus aureus. Such surface concentration may be achieved by passage of the diaper web through a bath of antimicrobial in a water or water/glycerine bath, the concentration of the antimicrobial being such as to provide the desired effective amount thereof. Passage through the bath and nip rolls at a rate appropriate to achieve an overall wet pickup of about 100 weight percent, based upon the weight of the fabric, is preferred. The impregnated fabric is then subjected to drying by passage through a dryer, typically through a stack of steam cans maintained at a suitable temperature that drying of the fabric may occur between about 200° and about 250° F, so as to dry the fabric quickly but without effecting antimicrobial activity of the compounds incorporated into the fabric. If the antimicrobial composition is applied as an alcohol solution, the drying temperature may be lowered. The dried, finished product is then led away from the dryer, rolled. cut to size, and stored, wrapped in plastic bags or the like.

The preparation of wet wipes in accordance with the invention may be similarly conducted, with the exception of the drying step. The wet wipe fabric may be any fabric conventionally used for this purpose, and the anti-microbial hop acid may preferably be incorporated in a suitable liquid, such as a glycerine or polyglycol solution, for impregnation into the wet wipe. The wipe should be passed through a bath of the liquid, and passed through a nip roll or other means to eliminate excess liquid, and then cut to the chosen size and packaged in a plastic container, bag, etc. The concentration of the antimicrobial hop acid should preferably exceed about 0.00002 to about 0.100 weight percent of the solution, so as to achieve an effective amount

thereof in the wipe at the time of usage. As in the preparation of diapers, the concentration of the antimicrobial should be sufficient to provide an effective amount thereof at the point of usage.

Although the present invention has been described in considerable detail with reference to certain preferred embodiments, one skilled in the art will appreciate that the present invention can be practiced by other than the preferred embodiments, which have been presented for purposes of illustration and not of limitation. For example, alternative methods of incorporation of the antimicrobial materials in the diapers, or in alternative materials, such as dressings or bandages, may be envisioned.

Therefore, the scope of the appended claims should not be limited to the description of the preferred embodiments contained herein.

INDUSTRIAL APPLICABILITY

The diapers and wet wipes of this invention are easily prepared using conventional apparatus and processes, employing hop acid antimicrobial materials which are derived from brewing processes by known methods.

- 11 -

5

15

5

CLAIMS

We claim:

 A method for inhibiting the growth of Staphylococcus aureus on infants comprising the step of:

diapering the infant with a diaper comprising an effective amount of an antimicrobial compound selected from the group consisting of tetrahydroiso-alpha acids, hexahydro-beta acids, and mixtures thereof.

- 2. The method of claim 1, wherein said diaper is a disposable diaper.
- The method of claim 2, wherein said compound is applied to the diaper dissolved in a liquid selected from the group consisting of water, alcohols, propylene glycol, glycerine, polyglycols, and mixtures thereof.
- A diaper containing an antimicrobial compound selected from the group consisting of tetrahydroiso-alpha acids, hexahydro-beta acids, and mixtures thereof.
- The diaper of claim 4, wherein said antimicrobial compound is present in sufficient quantity to inhibit the growth of Staphylococcus aureus in liquids with which it is in contact.
- 6. A cleansing wet wipe comprising an antimicrobial compound selected from the group consisting of tetrahydroiso-alpha acids, hexahydro-beta acids, and mixtures thereof, in a liquid selected from the group consisting of water, alcohols, propylene glycol, glycerine, polyglycols, and mixtures thereof.

 The cleansing wet wipe of claim 6, wherein said compound is present in sufficient quantity to inhibit the growth of Staphylococcus aureus in liquids with which it is in contact.

ABSTRACT OF THE DISCLOSURE

Diapers and wet wipes for cleansing of infants are made anti-bacterial by the inclusion therein of hop acid derivatives, specifically tetrahydroiso-alpha acid and hexahydro-beta acid. These compounds are effective to inhibit the growth of gram-positive bacteria, and specifically chosen to combat Staphylococcus aureus, a primary factor in toxic shock syndrome in infants.

EXPRESS MAIL LABEL NO. EJ636885455US

PTO/SB/01 (6-95) Approved for use through 9/30/98. OMB 0651-0032 and Trademark Office: U.S. DEPARTMENT OF COMMERCE

lease type a plus sign (+	Inside this box LLL	Patent and Tradem	iark Office: U.S. L	DEPARTMENT OF COMMERCE								
0010/PTO U.S Rev 6/95 Pater	Department of Commerce t and Trademark Office	Attorney Docket Numb	er 661005.9	0268								
		First Named Inventor	Michael C	. Barney								
DECLARA	TION FOR	COMPLETE IF KNOWN										
UTILITY C	R DESIGN	Application Number	pplication Number									
PATENT AF	PLICATION	Filing Date	Herewith	Herewith								
Davis of the Control	R Declaration	Group Art Unit										
X Submitted with Initial Filing	Submitted after Initial Filing	Examiner Name										
As a below named invent	or, I hereby declare that:											
My residence, post office address and chizzenship are as stated below next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural												
names are listed below) o	inal, first and sole inventor (i f the subject matter which is	f only one name is listed be claimed and for which a p	atent is sought on	first and joint inventor (if plural the invention entitled.								
	ANTIMICPORI	AL DIABERS AND W	ET WIDEC									
	ANTIMICROBIAL DIAPERS AND WET WIPES											
the specification of which		(Title of the Invention)										
X is attached hereto												
OR was filed on (MM/DD/YYYY)	3	as U	Inited States Application	n Number or PCT International								
Application Number	1	amended on (MM/DD/YYYY)		(if applicable)								
	yed and understand the contents of											
referred to above	ose information which is material to											
I hereby claim foreign priori	ry benefits under Title 35, Unit	ed States Code §119(a)-(d) o	or \$365(b) of any for	eign application(s) for patent or other than the United States of								
	ave also identified below, by c n having a filing date before th			nt or inventor's certificate, or any								
Prior Foreign Application Number(s)	Country	Foreign Filing Di (MM/DD/YYY)		Certified Copy Attached? YES NO								
N/A												
			IЙ									
			1 1									
1	cations numbers are listed on a											
	t under Title 35, United States											
Application Number	ir(s) Filing Di	ate (MM/DD/YYYY)	numbers	l provisional application are listed on a supplemental neet attached hereto.								
IV/A			p, e.									

Barden Hour Statement: The form is estimated to take 4 hours to complete. Time will very reporting upon the seed of the individual case Any comments on the amount of time you are required to complete the form should be used to sent to see Chair Individual Case Any comments on the amount of time you are required to complete the form should be used to sent to see Chair Individual Case Any Carden and Trademark Offices, Washington, DC 20231 Do NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO 'Assistant Commissioner for Platents, Washington, DC 20231

DE	CLA	RA1	TION

Page 2

hereby claim benefit under Title 35, United States Code §120 of any United States application(s), or
§365(C) of any PCT international application designating the United States of America, listed below and
insofar as the subject matter of each of the claims of this application is not disclosed in the prior United
States application or PCT international application in the manner provided in the first paragraph of Title
35, United States Code §112, I acknowledge the duty to disclose information which is material to
patentability as defined in Title 37, Code of Federal Regulations §1.56 which became available between
the filing date of the prior application and the national or PCT international filing date of this application

States a 35, Uni patental	pplication or PC ited States Code bility as defined	T internatio §112, I ac in Title 37.	nal application knowledge the Code of Feder	in t dut al F	the manner provid by to disclose infor Regulations § 1.56 or PCT internation	ed in matio which	the fi n whi n beca	rst para ch is ma me ava	graph aterial ilable	of Title to between
U.S. Pa	rent Application Number	Р	CT Parent Number		Parent Filing Date Parent Pare				ent Nu	
	N/A									
Ad	lditional U.S. or PC	T internationa	al application num	ber	s are listed on a supp	lemen	tal pric	ority shee	et atta	ched hereto
applica:	tion and all cor	ntinuation a	ind divisional	app	ing attorney(s) a plications based t nected therewith	here				
	m Name OR : attorney(s) and/or	agent(s) nam	ne and registratio	n nu	umber below	Cus Nun	tomer nber	or label		
	Name		Registration Number		TOTAL CONTRACTOR OF THE PARTY O	Nam	е			Registration Number
Herbert Barry E Nichola George Michae Carl R. Keith M	s W. Ehrmann t W. Mylius . Sammons is J. Seay E. Haas I J. McGovern Schwartz d. Baxter . Franzini . Baker		20,374 24,578 25,608 27,386 27,642 28,326 29,437 31,233 31,356 35,433		David G. Ryser Bennett J. Berson Michael A. Jaskolski Richard T. Roche John T. Pienkos Daniel G. Radler Gregory M. Smith Steven J. Wietrzny David M. Kettner Adam J. Forman					36,407 37,094 37,551 38,599 42,997 43,028 43,136 44,402 45,589 46,707
	Additional attorney(s) and/or ager	nts named on a su	pple	emental priority sheet	attache	d here	to		
Please dire	ct all corresponden	ce to	Customer Number or labe	el		OR	×	Fill in co	rrespo	ndence
Name	David G. Ryse	er								
Address	Quarles & Bra	ady LLP								
Address	411 Fast Wise	consin Aver	nue. Suite 204	n -						

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeoparcite the validity of the application or any patent is suring thereon.

Telephone

State WI

414) 277-5717

Zip

Fax

53202-4497

(414) 271-3552

Nam	ne of \$	Sole	or First Inventor:						A petition	has been file	d for this u	ınsigne	d invent	or
Give		М	lichael		Middle Initial	C	. F	amily lame	Barney			Suffix e.g. Jr.		
Inven	tor's		Michael () Be	w	ey					Date	10/10	1200	0
Resi	idence	e:	Elm Grove			V	Sta	te W	/I Country	USA	Citize	enship	USA	4
Post	Offic	e:	15155 Westo	ver Roa	d									
Post	Offic	е												
City Elm Grove State WI						Zip	530	92	Country	USA		App	olicant hority	
	x	Add	itional inventors are	heing nan	ned on	sunn	lemen	al she	et(s) attach	ed hereto				

City

Country

Milwaukee

DECLARATION						ADDITIONAL INVENTOR(S) Supplemental Sheet						
Name of	Additional Joint Inventor, if a	ny					A peti	tion has beei	n filed for th	nis ur	isigned in	rventor
Given Name	Alfonso	M	fiddle utial	ņ.m	i. Fami Nam	ly e	Navarr	0			Suffix	
Inventor's Signature		(eys non					Di	ate	10/1	- 5/ov
Residenc	e: Milwaukee		/		State	wi	Country	USA	(Citize	enship	Spain
Post Office	te 1129 North Jacks	son S	tree	t, #1	413-C							
Post Offic	e e											
City N	1ilwaukee	State	wı	Zip	5320	2	Country	USA			Appl Auth	cant ority
Name of	Additional Joint Inventor, if a	any					A pet	tion has bee	n filed for t	his ui	nsigned i	nventor
Given Name	David	\ P	/iddle	S.	Fami Nam	ly)	Ryder				Suffix e.g. Jr	
Inventor's Signature	Q,) a	jsl			le.	√·		D	ate	10-	10-00
Residence	e: Mequon				State	W	/I Countr	USA	Citizensh	ııp L	Jnited	Kingdon
Post Office	ce 10727 North Ga	zebo	Hills	Park	way							
Post Offic	ce											
City M	equon	State	WΙ	Zip	5309	2	Country	USA			Appl Auth	icant ority
Name of	Additional Joint Inventor, if	any.					A pet	ition has bee	n filed for t	his u	nsigned i	nventor
Given Name			Midd	ile al	Ę	amily ame	′				Suffix e.g. Jr	
Inventor's Signature									D	ate		
Residenc	e:				State		Country			Citiz	enship	
Post Offic	ce											
Post Offic	ce											
City		State		Zıp			Country				Appl Autr	icant iority
Name of	Additional Joint Inventor, if	any					A pet	ition has bee	n filed for	this u	nsigned i	nventor
Given Name		N Ir	Aiddle nitial	,	Fam Nan	ily 1e					Suffix e.g. Jr	
Inventor's Signature									D	ate		
Residenc	pe .				State		Country	,		Citı	zenship	
Post Off	ice											
Post Off	ice											
City		State		Zip			Country				Appl	licant lority
	Additional inventors are bei	ing nan	ned c	n sup	plement	al sh	eet(s) attac	hed hereto				